



5-28-04

Attorney's Docket No.: 16743-004001 / 12A-921112

IFC \$1

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : You-Di Liao

Art Unit : Unknown

Serial No. : 10/813,549

Examiner : Unknown

Filed : March 29, 2004

Title : REMOVAL OF N-TERMINAL METHIONINE FROM PROTEINS BY  
ENGINEERED METHIONINE AMINOPEPTIDASE

Commissioner for Patents

P.O. Box 1450

Alexandria, VA 22313-1450

INFORMATION DISCLOSURE STATEMENT

In accordance with the duty of disclosure as set forth in 37 C.F.R. §1.56, Applicants hereby submit the following information in conformance with 37 C.F.R. §§ 1.97 and 1.98.

Pursuant to 37 C.F.R. § 1.98, a copy of each of the documents cited is enclosed. However, copies of the listed U.S. patents and U.S. patent application publications are not enclosed since it is no longer required to submit copies of cited U.S. patents and U.S. patent application publications in national patent applications filed after June 30, 2003, according to the July 11, 2003 waiver of the requirement.

**United States Patents/ Patent Publications**

1. U.S. Patent No. 5,013,662

**Articles**

2. Abe, A., *et al.* (2000) Acetylation at the N-terminus of actin strengthens weak interaction between actin and myosin. *Biochem. Biophys. Res. Commun.*, 268:14-19.
3. Adachi, K., *et al.* (2000) Expression of functional soluble human  $\alpha$ -globin chains of hemoglobin in bacteria. *Protein Expr. Purif.*, 20:37-44.
4. Belagaje, R.M., *et al.* (1997) Increased production of low molecular weight recombinant proteins in *Escherichia coli*. *Protein Sci.*, 6:1953-1962.
5. Ben-Bassat, A., *et al.* (1987) Processing of the initiation methionine from proteins: properties of the *Escherichia coli* methionine aminopeptidase and its gene structure. *J. Bacteriol.*, 169(2):751-757.

**CERTIFICATE OF MAILING BY EXPRESS MAIL**

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May 26, 2004

Date of Deposit

6. Boix, E., *et al.* (1996) Role of the N terminus in RNase A homologues: differences in catalytic activity, ribonuclease inhibitor interaction and cytotoxicity. *J. Mol. Biol.*, 257:992-1007.
7. Busby, W.H., Jr., *et al.* (1987) An enzyme(s) that converts glutaminyl-peptides into pyroglutamyl-peptides. Presence in pituitary, brain, adrenal medulla, and lymphocytes. *J. Biol. Chem.*, 262(18):8532-8536.
8. Chang, S.Y., *et al.* (1989) Methionine aminopeptidase gene of *Escherichia coli* is essential for cell growth. *J. Bacteriol.*, 171(7):4071-4072.
9. Chen, S., *et al.* (2002) The specificity *in vivo* of two distinct methionine aminopeptidases in *Saccharomyces cerevisiae*. *Arch. Biochem. Biophys.*, 398(1):87-93.
10. Chiu, C.H., *et al.* (1999) Amino acid residues involved in the functional integrity of *Escherichia coli* methionine aminopeptidase. *J Bacteriol* 181(15):4686-4689.
11. Endo, S., *et al.* (2001) The additional methionine residue at the N-terminus of bacterially expressed human interleukin-2 affects the interaction between the N- and C-termini. *Biochemistry*, 40:914-919.
12. Fischer, W.H., and Spiess, J. (1987) Identification of a mammalian glutaminyl cyclase converting glutaminyl into pyroglutamyl peptides. *Proc. Natl. Acad. Sci. U.S.A.*, 84:3628-3632.
13. Hirel, P.H., *et al.* (1989) Extent of N-terminal methionine excision from *Escherichia coli* proteins is governed by the side-chain length of the penultimate amino acid. *Proc. Natl. Acad. Sci. U.S.A.*, 86:8247-8251.
14. Huang, H.C., *et al.* (1998) The *Rana catesbeiana rcr* gene encoding a cytotoxic ribonuclease. Tissue distribution, cloning, purification, cytotoxicity, and active residues for RNase activity. *J. Biol. Chem.*, 273(11):6395-6401.
15. Hwang, D.D.W., *et al.* (1999) Co-expression of glutathione S-transferase with methionine aminopeptidase: a system of producing enriched N-terminal processed proteins in *Escherichia coli*. *Biochem. J.*, 338(Pt 2):335-342.
16. Ishitani, M., *et al.* (2000) SOS3 function in plant salt tolerance requires N-myristoylation and calcium binding. *Plant Cell*, 12:1667-1677.
17. Leu, Y.J., *et al.* (2003) Residues involved in the catalysis, base specificity, and cytotoxicity of ribonuclease from *Rana catesbeiana* based upon mutagenesis and X-ray crystallography. *J. Biol. Chem.*, 278(9):7300-7309.

18. Li, X., and Chang, Y.H. (1995) Amino-terminal protein processing in *Saccharomyces cerevisiae* is an essential function that requires two distinct methionine aminopeptidases. *Proc. Natl. Acad. Sci. U.S.A.*, 92:12357-12361.
19. Liao, Y.D., and Wang, J.J. (1994). Yolk granules are the major compartment for bullfrog (*Rana catesbeiana*) oocyte-specific ribonuclease. *Eur J Biochem.*, 222:215-220.
20. Liao, Y.D., *et al.* (2000) Purification and cloning of cytotoxic ribonucleases from *Rana catesbeiana* (bullfrog). *Nucleic Acids Res.*, 28(21):4097-4104.
21. Liao, Y.D., *et al.* (2003) The structural integrity exerted by N-terminal pyroglutamate is crucial for the cytotoxicity of frog ribonuclease from *Rana pipiens*. *Nucleic Acids Res.*, 31(18):5247-5255.
22. Lowther, W.T., *et al.* (1999) *Escherichia coli* methionine aminopeptidase: implications of crystallographic analyses of the native, mutant, and inhibited enzymes for the mechanism of catalysis. *Biochemistry*, 38:7678-7688.
23. Lowther, W.T., and Matthews, B.W. (2000) Structure and function of the methionine aminopeptidases. *Biochim. Biophys. Acta.*, 1477:157-167.
24. Moerschell, R.P., *et al.* (1990) The specificities of yeast methionine aminopeptidase and acetylation of amino-terminal methionine *in vivo*. Processing of altered iso-1-cytochromes *c* created by oligonucleotide transformation. *J. Biol. Chem.*, 265(32):19638-19643.
25. Notomista, E., *et al.* (1999) Effective expression and purification of recombinant onconase, an antitumor protein. *FEBS Lett.*, 463:211-215.
26. Prchal, J.T., *et al.* (1986) Hemoglobin Long Island is caused by a single mutation (adenine to cytosine) resulting in a failure to cleave amino-terminal methionine. *Proc. Natl. Acad. Sci. U.S.A.*, 83:24-27.
27. Roderick, S.L., and Matthews, B.W. (1993) Structure of the cobalt-dependent methionine aminopeptidase from *Escherichia coli*: a new type of proteolytic enzyme. *Biochemistry*, 32:3907-3912.
28. Shapiro, R., *et al.* (1988) Expression of Met-(-1) angiogenin in *Escherichia coli*: conversion to the authentic <Glu-1 protein. *Anal. Biochem.*, 175:450-461.
29. Tahirov, T.H., *et al.* (1998) Crystal structure of methionine aminopeptidase from hyperthermophile, *Pyrococcus furiosus*. *J. Mol. Biol.*, 284:101-124.
30. Tobias, J.W., *et al.* (1991) The N-end rule in bacteria. *Science*, 254:1374-1377.

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Page : 4 of 4

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31. Varshavsky, A. (1996) The N-end rule: functions, mysteries, uses. Proc. Natl. Acad. Sci. U.S.A., 93:12142-12149.
32. Vetro, J.A., and Chang, Y.H. (2002) Yeast methionine aminopeptidase type 1 is ribosome-associated and requires its N-terminal zinc finger domain for normal function *in vivo*. J. Cell. Biochem., 85:678-688.
33. Walker, K.W., and Bradshaw, R.A. (1999) Yeast methionine aminopeptidase I. Alteration of substrate specificity by site-directed mutagenesis. J. Biol. Chem., 274(19):13403-13409.

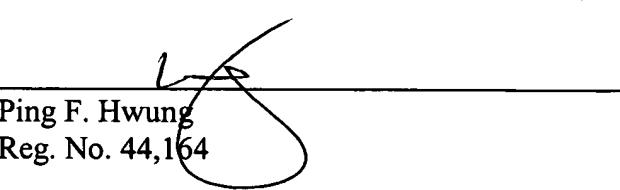
This Information Disclosure Statement is being submitted within three (3) months of the filing date or before any office action is issued. Consequently, no fee is required pursuant to 37 C.F.R. §1.97(b).

By citing the above references, Applicants do not acquiesce or admit that any of these documents is "prior art" under 35 U.S.C. Applicants specifically reserve the right, where appropriate, to antedate any of the cited documents by an appropriate showing under 37 C.F.R. §1.131, §1.604, §1.608 or any other suitable means.

To assist the Examiner, the documents are listed on the attached form PTO-1449. It is respectfully requested that an Examiner initialed copy of this form be returned to the undersigned. Please apply any charges or credits to Deposit Account No. 06-1050.

Respectfully submitted,

Date: May 26, 2004

  
Ping F. Hwung  
Reg. No. 44,164

Fish & Richardson P.C.  
500 Arguello Street, Suite 500  
Redwood City, California 94063  
Telephone: (650) 839-5070  
Facsimile: (650) 839-5071



# TRANSMITTAL FORM

(be used for all correspondence after initial filing)

		Application Number	10/813,549
		Filing Date	March 29, 2004
		First Named Inventor	You-Di Liao
		Group Art Unit	Unknown
		Examiner Name	Unknown
Total Number of Pages in this Submission	12 (plus 32 references)	Attorney Docket Number	16743-004001

## ENCLOSURES (check all that apply)

<input checked="" type="checkbox"/> Fee Transmittal Form <input checked="" type="checkbox"/> Fee Attached  <input type="checkbox"/> Amendment / Response <input type="checkbox"/> After Final  <input checked="" type="checkbox"/> Combined Declaration and Power of Attorney  <input type="checkbox"/> Extension of Time Request  <input type="checkbox"/> Express Abandonment Request  <input checked="" type="checkbox"/> Information Disclosure Statement  06/01/2004 JIBALINAN 00000009 10813549 03 C:2051 <input type="checkbox"/> Certified Copy of Priority Document(s) 65.00 0P  <input type="checkbox"/> Response to Missing Parts/ Incomplete Application  <input type="checkbox"/> Response to Missing Parts under 37 CFR 1.52 or 1.53	<input type="checkbox"/> Assignment Papers (for an Application) <input type="checkbox"/> Drawings <input type="checkbox"/> Licensing-related Papers <input type="checkbox"/> Petition Routing Slip (PTO/SB/69) and accompanying Petition <input type="checkbox"/> Petition to Convert to a Provisional Application <input type="checkbox"/> Power of Attorney, Revocation Change of Correspondence Address <input type="checkbox"/> Terminal Disclaimer <input type="checkbox"/> Small Entity Statement <input type="checkbox"/> Request for Refund	<input type="checkbox"/> After Allowance Communication to Group <input type="checkbox"/> Appeal Communication to Board of Appeals and Interferences <input type="checkbox"/> Appeal Communication to Group (Appeal Notice, Brief, Reply Brief) <input type="checkbox"/> Proprietary Information <input type="checkbox"/> Status Letter <input checked="" type="checkbox"/> Additional Enclosure(s) (please identify below):
<div style="border: 1px solid black; padding: 5px; text-align: center;">           PTO-1449 form and 32 references            Return receipt postcard         </div>		
<div style="border: 1px solid black; padding: 5px; text-align: center;">           Remarks         </div>		

## SIGNATURE OF APPLICANT, ATTORNEY OR AGENT

Firm or Individual name	Ping F. Hwung, Reg. No. 44,164
Signature	
Date	May 26, 2004

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# FEES TRANSMITTAL for FY 2004

Effective 10/01/2003. Patent fees are subject to annual revision.

 Applicant claims small entity status. See 37 CFR 1.27

TOTAL AMOUNT OF PAYMENT (\$ 477.00)

## Complete if Known

Application Number	10/813,549
Filing Date	March 29, 2004
First Named Inventor	You-Di Liao
Examiner Name	Unknown
Art Unit	Unknown
Attorney Docket No.	16743-004001

## METHOD OF PAYMENT (check all that apply)

 Check  Credit card  Money Order  Other  None
 Deposit Account:

Deposit Account Number  
06-1050

Deposit Account Name  
Fish & Richardson P.C.

The Director is authorized to: (check all that apply)

 Charge fee(s) indicated below  Credit any overpayments  
 Charge any additional fee(s) or any underpayment of fee(s)  
 Charge fee(s) indicated below, except for the filing fee to the above-identified deposit account.

## FEE CALCULATION

## 1. BASIC FILING FEE

Large Entity	Small Entity	Fee Code (\$)	Fee Code (\$)	Fee Description	Fee Paid
1001	770	2001	385	Utility filing fee	385
1002	340	2002	170	Design filing fee	
1003	530	2003	265	Plant filing fee	
1004	770	2004	385	Reissue filing fee	
1005	160	2005	80	Provisional filing fee	
SUBTOTAL (1) (\$)		385			

## 2. EXTRA CLAIM FEES FOR UTILITY AND REISSUE

Total Claims	Independent Claims	Multiple Dependent	Extra Claims	Fee from below	Fee Paid
23	1		-20** = 3	x 9 = 27	27
			- 3** = 3	x 43 = 0	0

Large Entity	Small Entity	Fee Description
1202	18	2202 9 Claims in excess of 20
1201	86	2201 43 Independent claims in excess of 3
1203	290	2203 145 Multiple dependent claim, if not paid
1204	86	2204 43 ** Reissue independent claims over original patent
1205	18	2205 9 ** Reissue claims in excess of 20 and over original patent
SUBTOTAL (2) (\$)		27

\*\*or number previously paid, if greater. For Reissues, see above

## 3. ADDITIONAL FEES

Large Entity	Small Entity	Fee Description	Fee Paid
1051	130	2051 65 Surcharge - late filing fee or oath	65
1052	50	2052 25 Surcharge - late provisional filing fee or cover sheet	
1053	130	1053 130 Non-English specification	
1812	2,520	1812 2,520 For filing a request for ex parte reexamination	
1804	920*	1804 920* Requesting publication of SIR prior to Examiner action	
1805	1,840*	1805 1,840* Requesting publication of SIR after Examiner action	
1251	110	2251 55 Extension for reply within first month	
1252	420	2252 210 Extension for reply within second month	
1253	950	2253 475 Extension for reply within third month	
1254	1,480	2254 740 Extension for reply within fourth month	
1255	2,010	2255 1,005 Extension for reply within fifth month	
1401	330	2401 165 Notice of Appeal	
1402	330	2402 165 Filing a brief in support of an appeal	
1403	290	2403 145 Request for oral hearing	
1451	1,510	1451 1,510 Petition to institute a public use proceeding	
1452	110	2452 55 Petition to revive - unavoidable	
1453	1,330	2453 665 Petition to revive - unintentional	
1501	1,330	2501 665 Utility issue fee (or reissue)	
1502	480	2502 240 Design issue fee	
1503	640	2503 320 Plant issue fee	
1460	130	1460 130 Petitions to the Commissioner	
1807	50	1807 50 Processing fee under 37 CFR 1.17(q)	
1806	180	1806 180 Submission of Information Disclosure Stmt	
8021	40	8021 40 Recording each patent assignment per property (times number of properties)	
1809	770	2809 385 Filing a submission after final rejection (37 CFR 1.129(a))	
1810	770	2810 385 For each additional invention to be examined (37 CFR 1.129(b))	
1801	770	2801 385 Request for Continued Examination (RCE)	
1802	900	1802 900 Request for expedited examination of a design application	
Other fee (specify) _____			

\*Reduced by Basic Filing Fee Paid

SUBTOTAL (3) (\$)

65

## SUBMITTED BY

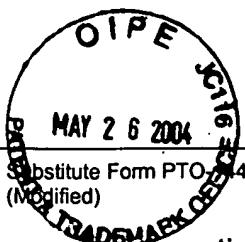
(Complete if applicable)

Name (Print/Type)	Ping F. Hwang	Registration No. (Attorney/Agent)	44,164	Telephone	(650) 839-5070
Signature				Date	May 26, 2004

WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.

This collection of information is required by 37 CFR 1.17 and 1.27. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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Substitute Form PTO-1449 (Modified)	U.S. Department of Commerce Patent and Trademark Office	Attorney's Docket No. 16743-004001	Application No. 10/813,549
<b>Information Disclosure Statement</b> <b>by Applicant</b> <small>(Use several sheets if necessary)</small> <small>(37 CFR §1.98(b))</small>		Applicant	You-Di Liao
		Filing Date March 29, 2004	Group Art Unit Unknown

U.S. Patent Documents							
Examiner Initial	Desig. ID	Document Number	Publication Date	Patentee	Class	Subclass	Filing Date If Appropriate
	AA	5,013,662	05/07/1991	Ben-Bassat, et al.			
	AB						
	AC						
	AD						
	AE						
	AF						
	AG						
	AH						
	AI						
	AJ						
	AK						

Foreign Patent Documents or Published Foreign Patent Applications							
Examiner Initial	Desig. ID	Document Number	Publication Date	Country or Patent Office	Class	Subclass	Translation Yes      No
	AL						
	AM						
	AN						
	AO						
	AP						

Other Documents (include Author, Title, Date, and Place of Publication)		
Examiner Initial	Desig. ID	Document
	AQ	Abe, A., et al. (2000) Acetylation at the N-terminus of actin strengthens weak interaction between actin and myosin. Biochem. Biophys. Res. Commun., 268:14-19.
	AR	Adachi, K., et al. (2000) Expression of functional soluble human $\alpha$ -globin chains of hemoglobin in bacteria. Protein Expr. Purif., 20:37-44.
	AS	Belagaje, R.M., et al. (1997) Increased production of low molecular weight recombinant proteins in <i>Escherichia coli</i> . Protein Sci., 6:1953-1962.

Examiner Signature	Date Considered
EXAMINER: Initials citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.	

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		Filing Date March 29, 2004	Group Art Unit Unknown	

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	AT	Ben-Bassat, A., <i>et al.</i> (1987) Processing of the initiation methionine from proteins: properties of the <i>Escherichia coli</i> methionine aminopeptidase and its gene structure. <i>J. Bacteriol.</i> , 169(2):751-757.
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	AAA	Fischer, W.H., and Spiess, J. (1987) Identification of a mammalian glutamyl cyclase converting glutamyl into pyroglutamyl peptides. <i>Proc. Natl. Acad. Sci. U.S.A.</i> , 84:3628-3632.
	ABB	Hirel, P.H., <i>et al.</i> (1989) Extent of N-terminal methionine excision from <i>Escherichia coli</i> proteins is governed by the side-chain length of the penultimate amino acid. <i>Proc. Natl. Acad. Sci. U.S.A.</i> , 86:8247-8251.
	ACC	Huang, H.C., <i>et al.</i> (1998) The <i>Rana catesbeiana rcr</i> gene encoding a cytotoxic ribonuclease. Tissue distribution, cloning, purification, cytotoxicity, and active residues for RNase activity. <i>J. Biol. Chem.</i> , 273(11):6395-6401.
	ADD	Hwang, D.D.W., <i>et al.</i> (1999) Co-expression of glutathione S-transferase with methionine aminopeptidase: a system of producing enriched N-terminal processed proteins in <i>Escherichia coli</i> . <i>Biochem. J.</i> , 338(Pt 2):335-342.
	AEE	Ishitani, M., <i>et al.</i> (2000) SOS3 function in plant salt tolerance requires N-myristoylation and calcium binding. <i>Plant Cell</i> , 12:1667-1677.
	AFF	Leu, Y.J., <i>et al.</i> (2003) Residues involved in the catalysis, base specificity, and cytotoxicity of ribonuclease from <i>Rana catesbeiana</i> based upon mutagenesis and X-ray crystallography. <i>J. Biol. Chem.</i> , 278(9):7300-7309.

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	AGG	Li, X., and Chang, Y.H. (1995) Amino-terminal protein processing in <i>Saccharomyces cerevisiae</i> is an essential function that requires two distinct methionine aminopeptidases. <i>Proc. Natl. Acad. Sci. U.S.A.</i> , 92:12357-12361.
	AHH	Liao, Y.D., and Wang, J.J. (1994). Yolk granules are the major compartment for bullfrog ( <i>Rana catesbeiana</i> ) oocyte-specific ribonuclease. <i>Eur J Biochem.</i> , 222:215-220.
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	AJJ	Liao, Y.D., <i>et al.</i> (2003) The structural integrity exerted by N-terminal pyroglutamate is crucial for the cytotoxicity of frog ribonuclease from <i>Rana pipiens</i> . <i>Nucleic Acids Res.</i> , 31(18):5247-5255.
	AKK	Lowther, W.T., <i>et al.</i> (1999) <i>Escherichia coli</i> methionine aminopeptidase: implications of crystallographic analyses of the native, mutant, and inhibited enzymes for the mechanism of catalysis. <i>Biochemistry</i> , 38:7678-7688.
	ALL	Lowther, W.T., and Matthews, B.W. (2000) Structure and function of the methionine aminopeptidases. <i>Biochim. Biophys. Acta.</i> , 1477:157-167.
	AMM	Moerschell, R.P., <i>et al.</i> (1990) The specificities of yeast methionine aminopeptidase and acetylation of amino-terminal methionine <i>in vivo</i> . Processing of altered iso-1-cytochromes c created by oligonucleotide transformation. <i>J. Biol. Chem.</i> , 265(32):19638-19643.
	ANN	Notomista, E., <i>et al.</i> (1999) Effective expression and purification of recombinant onconase, an antitumor protein. <i>FEBS Lett.</i> , 463:211-215.
	AOO	Prchal, J.T., <i>et al.</i> (1986) Hemoglobin Long Island is caused by a single mutation (adenine to cytosine) resulting in a failure to cleave amino-terminal methionine. <i>Proc. Natl. Acad. Sci. U.S.A.</i> , 83:24-27.
	APP	Roderick, S.L., and Matthews, B.W. (1993) Structure of the cobalt-dependent methionine aminopeptidase from <i>Escherichia coli</i> : a new type of proteolytic enzyme. <i>Biochemistry</i> , 32:3907-3912.
	AQQ	Shapiro, R., <i>et al.</i> (1988) Expression of Met-(1) angiogenin in <i>Escherichia coli</i> : conversion to the authentic <Glu-1 protein. <i>Anal. Biochem.</i> , 175:450-461.
	ARR	Tahirov, T.H., <i>et al.</i> (1998) Crystal structure of methionine aminopeptidase from hyperthermophile, <i>Pyrococcus furiosus</i> . <i>J. Mol. Biol.</i> , 284:101-124.
	ASS	Tobias, J.W., <i>et al.</i> (1991) The N-end rule in bacteria. <i>Science</i> , 254:1374-1377.
	ATT	Varshavsky, A. (1996) The N-end rule: functions, mysteries, uses. <i>Proc. Natl. Acad. Sci. U.S.A.</i> , 93:12142-12149.

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<b>Other Documents (include Author, Title, Date, and Place of Publication)</b>		
Examiner Initial	Desig. ID	Document
	AUU	Vetro, J.A., and Chang, Y.H. (2002) Yeast methionine aminopeptidase type 1 is ribosome-associated and requires its N-terminal zinc finger domain for normal function <i>in vivo</i> . <i>J. Cell. Biochem.</i> , 85:678-688.
	AVV	Walker, K.W., and Bradshaw, R.A. (1999) Yeast methionine aminopeptidase I. Alteration of substrate specificity by site-directed mutagenesis. <i>J. Biol. Chem.</i> , 274(19):13403-13409.

Examiner Signature	Date Considered
EXAMINER: Initials citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.	